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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

17027.003US1

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on November 9, 2006Signature Lynda MauTyped or printed name Lynda Mau

Application Number

09/903,412

Filed

July 11, 2001

First Named Inventor

Shohei Koide

Art Unit

1639

Examiner

T. Wessendorf

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒ attorney or agent of record.  
Registration number 37,748☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_Ann S. Viksnins  
SignatureAnn S. Viksnins  
Typed or printed name952-876-4091  
Telephone numberNovember 9, 2006  
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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S/N 09/903,412

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant :	Shohei Koide	Art Unit :	1639
Serial No. :	09/903,412	Examiner :	Teresa D. Wessendorf
Filed :	July 11, 2001	Docket:	17027.003US1
Title :	ARTIFICIAL ANTIBODY POLYPEPTIDES		

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This responds to the Final Office Action mailed on August 09, 2006. Applicant respectfully requests a Pre-Appeal Brief Conference to review the legal and factual basis of the claim rejections made in the Final Office Action. Applicant will amend the specification to remove the embedded hyperlink.

Submitted herewith are a Notice of Appeal and the appropriate fee.

Claims 1, 4, 7, 8 and 54-63 are pending.

A listing of the pending claims can be found at pages 3-5 in the Response submitted on May 02, 2006.

**I. The 35 U.S.C. § 112, First Paragraph "New Matter" Rejection of the Claims**

The Examiner rejected claims 54-63 under 35 U.S.C. § 112, first paragraph, alleging that those claims fail to comply with the written description requirement. The Examiner alleges that those claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the claimed "neutral" or "positively charged amino acid residue" are not supported in the specification as filed. The Examiner further alleges that the "open" amino acid residues at positions 7, 9 or 23 are not supported in the as-filed specification.

Applicant respectfully disagrees and submits that the originally-filed application provides sufficient support for those claims, *e.g.*, because the originally-filed application reasonably conveys to one having ordinary skill in the art that an Applicant had possession of the concepts of what is now claimed.

Applicant respectfully directs the Panel's attention to the comments at pages 6-7 in the Response submitted on May 02, 2006.

Thus, Applicant respectfully requests that the Panel withdraw the "new matter" rejection of claims 54-63.

## II. The 35 U.S.C. § 112, First Paragraph "Written Description" Rejection of the Claims

The Examiner rejected claims 1, 8 and 54-63 under 35 U.S.C. § 112, first paragraph, alleging that those claims fail to comply with the written description requirement. The Examiner alleges that those contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant respectfully disagrees and submits that the application as originally filed provides an adequate written description of the claimed invention. Applicant has provided structural characteristics of the claimed modified Fn3 molecules as the structure of wild-type Fn3 molecules were known to the art worker at the time the application was filed. Applicant has recited specific structural modifications to the known Fn3 molecule, *i.e.*, the modified Fn3 molecule has a substitution of at least one of amino acid residues 7, 9 or 23, *e.g.*, Asp 7, Asp 23 or Glu 9. Applicant has also recited functional characteristics of the claimed modified Fn3 molecules, namely, that the modified Fn3 molecules comprise a stabilizing mutation, which mutation is functionally described in the specification together with an assay to measure the functional characteristic. Applicant has further provided examples of stabilizing mutations of the recited amino acids. Thus, it is respectfully asserted that Applicant has provided adequate written description of the claimed modified Fn3 molecules as Applicant has disclosed in sufficient detail the relevant identifying structural and functional characteristics that provide

evidence that the Applicant was in possession of the full scope of the claimed invention at the time the application was filed.

Applicant respectfully directs the Panel's attention to the comments at pages 8-11 in the Response submitted on May 02, 2006.

Thus, Applicant respectfully requests that the Panel withdraw the "written description" rejection of claims 1, 8 and 54-63.

### III. The 35 U.S.C. § 103(a) Rejection of the Claims

The Examiner rejected claims 1, 4, 7-8 and 54-63 under 35 U.S.C. § 103(a), alleging that those claims are unpatentable over Koide (WO 98/56915; hereinafter Koide) or Lipovsek *et al.* (U.S. Patent No. 6,818,418; hereinafter Lipovsek) in view of Spector *et al.* (*Biochemistry*, 39, 872-879 (2000); hereinafter Spector).

Applicant respectfully submits that the Examiner has not demonstrated that the claims are *prima facie* obvious in view of the cited documents, for example, because the Examiner has not established that the cited documents teach or suggests all the claim limitations. And, even if, for the sake or argument, the cited documents teach or suggests all the claim limitations, Applicant respectfully submits that the Examiner has not established the suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention. Further, Applicant respectfully submits that the Examiner is improperly relying on an "obvious to try" standard.

For example, Applicant respectfully submits that the Examiner has not established that the cited documents, either alone or in combination, teach a modified Fn3 molecule comprising a stabilizing mutation of at least one residue involved in an unfavorable electrostatic interaction as compared to a wild-type Fn3, wherein the stabilizing mutation is a substitution of at least one of Asp 7, Asp 23 or Glu 9 with another amino acid residue. (*see* claim 1) Nor do the cited documents, either alone or in combination, teach a modified FNfn10 molecule comprising a stabilizing mutation of at least one residue involved in an unfavorable electrostatic interaction as

compared to a wild-type FNfn10 molecule, wherein the stabilizing mutation is a substitution of at least one of amino acid residues 7, 9 or 23 with another amino acid residue. (*see* claim 57)

Applicant respectfully directs the Panel's attention to the comments at pages 12-14 in the Response submitted on May 02, 2006.

Thus, Applicant respectfully submits that the cited documents, neither alone nor in combination, teach the claimed invention. Accordingly, Applicant respectfully requests that the Panel withdraw the rejection of the claims under 35 U.S.C. § 103(a).

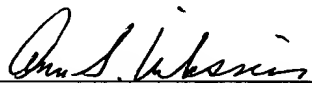
#### IV. Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is respectfully requested.


The Panel is invited to telephone Applicant's attorney to facilitate prosecution of this application. If necessary, please charge any additional required fees or credit any overpayments to Deposit Account No. 503503.

Respectfully submitted,  
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By his Representatives,  
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(952) 876-4091

Date: 9 November 2006

By:   
Ann S. Viksnins  
Reg. No. 37,748

CERTIFICATE UNDER 37 CFR 1.8: The undersigned certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9th day of November 2006.

  
Name

  
Signature